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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/489,667	01/19/00	DONOVAN S	D-2875

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EXAMINER	
KAM,C	
ART UNIT	PAPER NUMBER
1653	18

DATE MAILED: 07/11/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Offic Action Summary	Application No. 09/489,667	Applicant(s) DONOVAN, STEPHEN	
	Examiner Chih-Min Kam	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 April 2001* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *66-80* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *69-80* is/are allowed.

6)☒ Claim(s) *66-68* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *12* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Status of the Claims

1. Claims 66-80 are pending.

Applicants' response filed on April 26, 2001 (Paper No. 11) has been fully considered. Claims 1-65 have been cancelled, claim 66 has been amended, and new claims 67-80 have been added.

Rejection Withdrawn

Claim Rejections - 35 USC § 112

2. The previous rejection of claims 1-10, 12-13, 15-19 and 26-34, under 35 U.S.C.112, first paragraph, is withdrawn in view of applicants' cancellation of the claims and making changes in the new claims.

3. The previous rejection of claims 1-20 and 26-35, under 35 U.S.C.112, second paragraph, is withdrawn in view of applicants' cancellation of the claims and making changes in the new claims.

Claim Rejections - 35 USC § 102

4. The previous rejection of claims 1-9, 12, 18-19 and 26-35 under 35 U.S.C.102(b) as being anticipated by Foster *et al.* (WO 96/33273) is withdrawn in view of applicants' cancellation of the claim and applicants' response cited on pages 6 and 7 in Paper No:11.

5. The previous rejection of claims 1-9, 12, 18-19 and 26-35 under 35 U.S.C.102(e) as being anticipated by Foster *et al.* (US Patent 5,989,545), is withdrawn in view of applicants' cancellation of the claim and applicants' response cited on pages 6 and 7 in Paper No:11.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 67 and 68 are rejected under 35 U.S.C. 112, first paragraph.

Claims 67 and 68 are rejected because the specification, while being enabling for an agent comprising a clostridial neurotoxin component covalently attached to substance P, does not reasonably provide enablement for an agent comprising a clostridial neurotoxin component covalently attached to a precursor of substance P or a substance P analogue. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Claims 67 and 68 are drawn to encompass an agent comprising a clostridial neurotoxin component covalently attached to any precursor of substance P (claim 67) or any substance P analog (claim 68). The specification, however, only discloses cursory conclusions (see page 17, lines 1-3), without data to support the findings, which states that substance P precursors or analogues can be used as a target moiety in the agent for treating pain. Table 1 merely indicates some known substance P precursors and analogues, there is no data indicating an agent comprising a clostridial neurotoxin component covalently attached to the precursor or analog of substance P actually being made and used for treating pain. Despite knowledge in the art for substance P, the claims encompass many substance P precursors or analogs as the targeting moiety of an agent, it is not expected to be known whether the agent containing substance P analogues or precursors work in the same manner as the agent containing substance P. Since it is

not routine in the art to engage in *de novo* experimentation where the expectation of success is unpredictable, the skilled artisan would require additional guidance in order to make and use such agent in a manner reasonably commensurate with the scope of the claims. Without such guidance, the experimentation left to those skilled in the art is undue.

The factors considered in determining whether undue experimentation is required, are summarized in In re Wands (858 F2d at 731,737, 8 USPQ2d at 1400,1404 (Fed. Cir.1988)). The factors most relevant to this rejection are the scope of the claims, lacking of working examples, the amount of direction or guidance presented, and the amount of experimentation necessary.

Regarding enablement to make and use an agent comprising any transmission compound other than substance P as a target moiety, applicants indicate the specification has disclosed the making and use of various types of transmission compounds (page 5, paragraph 4 of Paper No. 11). However, the argument is not persuasive because the specification only shows various known substance P precursors or analogs are available to be a target moiety (page 17, lines 1-3; pages 25-27, Table 1), there is no data indicating the agent of a clostridial neurotoxin component covalently attached to the precursor or analog of substance P being made or used for treating pain. Therefore, the specification is not enabling for an agent of a clostridial neurotoxin component covalently attached to a substance P analogue or precursor.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 66 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite because of the use of the term "(a) a botulinum toxin type A proteolytic domain covalently attached to;".

The term "(a) a botulinum toxin type A proteolytic domain covalently attached to;" renders the claim indefinite, it is unclear to what the proteolytic domain is covalently attached, e.g., is it the translocation domain of part (b) or substance P of part (c)?

In response, applicants argue the claim clearly states the agent is attached as (proteolytic domain)-(translocation domain)-(substance P) (page 6 paragraph 4 of Paper No. 11). However, the argument is not persuasive because the claim does not indicate where the proteolytic domain is attached to, it can be either (b) or (c).

8. Claim 67 is indefinite because of the use of the term "precursor". The term "precursor" renders the claim indefinite, it is unclear what kind of peptide is intended for the precursor of substance P.

9. Claim 68 is indefinite because of the use of the term "analogue". The term "analogue" renders the claim indefinite, it is unclear what kind of peptide is intended for the analogue of substance P.

Conclusion

10. Claims 66-68 are rejected, it appears claims 69-80 are allowable.

Applicant's amendment of new claims 67-80 necessitated the new ground(s) of rejection presented in this office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, Ph. D. can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D.
Patent Examiner

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July 5, 2001

Christopher S. F. Low
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